

NOV 27 1996

**510 (k) SUMMARY: Microsurge Laparoscopic
PermaClip™ Cartridge with Implantable Titanium Clips**

- (1) Microsurge, Inc.
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Contact Person: Richard Lariviere
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- (2) Trade or Proprietary Name: Microsurge Laparoscopic
PermaClip™ Cartridge with
Implantable Titanium Clips

Common Name: Laparoscopic Clip Cartridge with
Implantable Titanium Clips

Classified Name: Implantable Clip (74FZP), 21 CFR
878.4300, Class II

- (3) Predicates: United States Surgical Corporation

Ethicon Endosurgery
Pilling Weck

(4) Description of Device:

The Microsurge Laparoscopic PermaClip™ Cartridge with implantable titanium clips is a disposable single patient use device fabricated from biocompatible stainless steels and biocompatible medical grade polymers. The PermaClip™ cartridge contains up to 12 implantable titanium clips. The closed clip length is approximately 9 mm. The device is designed to be used in conjunction with a separately supplied

reusable PermaClip™ Multi-Use Clip Applier to occlude blood vessels and other tubular structures during laparoscopic surgical procedures. The clip cartridge is attached to the clip applier handle via a lock/release mechanism, and inserted through a trocar to gain laparoscopic access. The clip cartridge jaws with the open clip in the jaws is placed around the vessel or other tubular structure. Actuation/compression of the clip applier handle/trigger drives a mechanism within the cartridge to close the cartridge jaws, thereby forming the clip securely around the vessel. Release/decompression of the clip applier handle/trigger allows the jaws of the cartridge to open and releases the clip from the cartridge jaws. The automatic feeding cartridge releases the next clip into the jaws for another application.

The cartridge is sized to fit through a 10 mm cannula. The overall shaft length of the cartridge plus the clip applier handle is approximately 33 mm, consistent with other endoscopic instruments.

(5) Intended Use:

The PermaClip™ Cartridge with implantable titanium clips is intended for use during laparoscopic surgery to occlude a variety of vessels or other tubular structures.

(6) Technological Characteristics:

The PermaClip™ Cartridge with implantable titanium clips has similar/same technological characteristics as the predicate devices in that they are comprised of similar design, materials, and are intended for use to clip vessels or tubular structures during laparoscopic surgery.

(7) Conclusion:

The new device has the same intended use and the same basic technology as the predicates identified in the premarket notification submission. The new device contains in some combination similar/same features, materials, and design as the predicates and does not pose any new questions concerning safety and effectiveness.